

REMARKS

Claims 1-12 are pending. Claims 1, 2, 4, 9, 10, 11, and 12 have been amended. Claim 13 has been added. As a result, Claims 1-13 are currently at issue. No new matter has been added.

The amendments to Claims 2, 4, and 11 are made to correct typographical errors, and not in response to any rejection or objection by the Examiner. These amendments do not alter the scope of Claims 2, 4, or 11.

A. Rejections Under 35 U.S.C. § 112

In paragraph 4 of the Office Action, the Examiner rejected Claim 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner questions whether Claim 12 is independent or dependent on Claim 1, and treated Claim 12 as dependent for examination purposes. Applicant confirms that Claim 12 is an independent claim, but has amended Claim 12 to positively recite the elements of Claim 1 for clarification purposes. Accordingly, Applicant submits that Claim 12 is in proper form, and respectfully requests reconsideration and withdrawal of the Examiner's rejection.

In paragraph 5 of the Office Action, the Examiner rejected Claims 4-7 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner rejected Claim 4 as indefinite because it refers to "said complementary means," which the Examiner asserts is not an element of Claim 1. Applicant respectfully submits that the element in Claim 1, "stop means adapted to cooperate with complementary means," incorporated said complementary means as an element of Claim 1. Nevertheless, Applicant has amended Claim 1 to require "a complementary means," to further clarify that said complementary means is intended to be an element of Claim 1. Because this amendment is made for clarification purposes, it is not intended to narrow the scope of Claim 1. Accordingly, Applicant submits that Claim 4 is in proper form. Additionally, because Claim 4 is in proper form, Claims 5-7 are also in proper form. Thus, Applicant respectfully requests reconsideration and withdrawal of the Examiner's rejection.

In paragraph 6 of the Office Action, the Examiner rejected Claims 9-10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner found that Applicant's use of the word "it" rendered the claims vague and indefinite. In response, Applicant has amended Claims 9 and 10 to clearly indicate the subject matter being claimed. Such amendments are made to clarify the intended meaning of the claims, and do not alter the scope of the claims. Applicant submits that Claims 9 and 10 are now clear and definite in scope and respectfully requests reconsideration and withdrawal of the Examiner's rejection.

B. Claim Rejections under 35 U.S.C. § 103

1. Rejection Over Aneas in View of Pfleiderer

In paragraph 7 of the Office Action, the Examiner rejected Claims 1-3, 6-8, 10, and 12 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,070,623 to Aneas ("Aneas") in view of U.S. Patent No. 5,636,660 to Pfleiderer *et al.* ("Pfleiderer"). Applicant respectfully traverses the Examiner's rejection.

The law is clear that "[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Further, the law is clear that there must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the modification suggested by Examiner. "[T]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." *In re Laskowski et. al.*, 10 U.S.P.Q. 2d 1397, 1398, (Fed. Cir. 1989), *citing In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). That motivation cannot come from the Applicant's invention itself. *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). Thus, unless the references suggest the particular combination of elements themselves, they cannot render Applicant's invention obvious. *In re Mahurkar Patent Litigation*, 831 F.Supp. 1354, 1374, 28 U.S.P.Q.2d 1801, 1817 (N.D. Ill. 1993). Applicant respectfully submits that the neither Aneas nor Pfleiderer, alone or in combination, disclose or suggest all the elements of Claims 1-3, 6-8, 10, and 12. Further, Applicant submits that Aneas and Pfleiderer are not properly combinable.

Claim 1 of the present application includes, among other elements, "said needle presents a non-circular outer cross-section, while said sleeve presents a likewise non-circular inner cross-section, the outer section of said needle and inner section of said sleeve being such that said needle can slide in said sleeve, without the possibility of rotation in said sleeve." Neither Aneas nor Pfleiderer discloses or suggests this element of Claim 1.

Aneas discloses a connection device for connecting two receptacles, which includes a perforating means (5) that slides with a plunger (15) in a skirt (12) having an internal bore (12a). (Aneas, Col. 4, Lines 28-47). Rotation of the plunger and perforating means is prevented by the use of grooves on the inner surface of the skirt and complementary ribs on the outer surface of the plunger. (Aneas, Col. 4, Lines 41-47). Aneas does not disclose the use of a non-circular needle or a non-circular sleeve to prevent rotation of the needle. Pfleiderer discloses a device for transferring and drawing liquids from containers, including two spikes (1, 2) having oval or other non-rotationally-symmetric shape, which it claims will prevent rotation of the spikes (1, 2) in the rubber-like bottle closures. (Pfleiderer, Col. 5, Lines 10-15). However, Pfleiderer does not disclose the use of a sleeve through which the needle slides. Thus, Pfleiderer also does not disclose making such a sleeve non-circular in shape to prevent a non-circular needle from rotating within the sleeve. Rather, the non-circular spike of Pfleiderer is designed to prevent rotation of the spike within the bottle closures (i.e. stoppers). Since neither Pfleiderer nor Aneas discloses the above limitation of Claim 1, the Examiner has not made a *prima facie* case of obviousness with respect to Claim 1.

Additionally, Claim 1 of the present application includes, among other elements, "an edge of said sleeve opposite said stopper is provided with stop means adapted to cooperate with a complementary means provided on said plunger to lock it in position of transfer." Pfleiderer does not disclose a sleeve or a plunger, and thus is not relevant to this element of Claim 1. Aneas discloses a connection device for connecting two receptacles, which includes a perforating means (5) that slides with a plunger (15) in a skirt (12) having an internal bore (12a). (Aneas, Col. 4, Lines 28-47). Aneas does disclose a means (16) for stopping the plunger (15), which includes one or more clipping members (17) on the plunger (15) and one or more complementary stop members (18) on the skirt (12). (Aneas, Col. 4, Lines 48-67). However, as illustrated in FIG. 1 of Aneas, the stop members (18) on the skirt (12) are positioned immediately adjacent to

the stopper (3), rather than at the “edge of said sleeve opposite said stopper,” as required by Claim 1. As illustrated in FIGS. 2, 5, and 7 of the present application, the sleeve (16) contains stop means (16a, 16b) at the edge of the sleeve opposite the stopper (3), which cooperate with complementary means (22) on the plunger (20) to lock the plunger in position. Accordingly, neither Aneas nor Pfleiderer discloses or suggests the above element of Claim 1, and thus, the Examiner has not made a *prima facie* case of obviousness of Claim 1.

Further, Aneas and Pfleiderer are not properly combinable to form a *prima facie* case of obviousness, because there is no suggestion or motivation to combine the references. First, the non-circular spike of Pfleiderer is designed to prevent rotation of the spike within the bottle closures (i.e. stoppers). (Pfleiderer, Col. 5, Lines 10-15). Preventing such rotation is not necessary in Aneas, since the connection device of Aneas is fastened to the bottle. (Aneas, Col. 4, Lines 10-27). Thus, there would be no motivation to combine the teachings of Aneas and Pfleiderer to render the invention of Claim 1 obvious. Second, Pfleiderer does not disclose the use of a skirt, sleeve, bore, or any similar structure, through which a needle slides. Thus, there would be no motivation to apply the teachings of Pfleiderer to a connection device using a needle that moves within a skirt, such as that of Aneas. The Examiner points to no teaching or suggestion in the prior art providing motivation to combine the teachings of Aneas and Pfleiderer. Accordingly, Aneas and Pfleiderer cannot be properly combined, and the Examiner has not set forth a *prima facie* case of obviousness with respect to Claim 1.

Claims 2, 3, 6-8, and 10 all depend from Claim 1 and, therefore, contain all the elements of Claim 1. Accordingly, for the reasons stated above with respect to Claim 1, the Examiner has not made a *prima facie* case of obviousness with respect to Claims 2, 3, 6-8, and 10.

Claim 12 is independent, but includes among its elements a connection device containing all the elements of Claim 1. Accordingly, for the reasons stated above with respect to Claim 1, the Examiner has not made a *prima facie* case of obviousness with respect to Claim 12.

2. Rejection Over Aneas

In paragraph 8 of the Office Action, the Examiner rejected Claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Aneas. Applicant respectfully traverses the Examiner's rejection.

Claim 9 depends from Claim 1 and includes all elements of Claim 1. As discussed above with respect to Claim 1, Aneas does not disclose or suggest all the elements of Claim 1. Furthermore, the ribs disclosed in Aneas are not “rigidifying ribs” as recited in Claim 9. The ribs (17) of Claim 9 rigidly connect the inner sleeve (16) to the outer sleeve (11), since both sleeves (11, 16) and the ribs (17) are formed together in a single piece. (See P.6, Lines 5-6; P.9, Line 25; FIG. 5). In contrast, the ribs of Aneas are not “connecting” the skirt (12) and the plunger (15), nor are they “rigidifying,” because the ribs in Aneas allow movement of the plunger (15) parallel to the axis of the device. The ribs in Aneas are not disclosed to add rigidity, and are only disclosed to block rotation of the plunger (15). (Aneas, Col. 4, Lines 41-47). Therefore, for the reasons set forth above with respect to Claim 1, the Examiner has not made a *prima facie* case of obviousness with respect to Claim 9.

3. Rejections Over Aneas in View of Pfleiderer and Martin

In paragraph 9 of the Office Action, the Examiner rejected Claims 4 and 5 under 35 U.S.C. § 103(a) as being unpatentable over Aneas in view of Pfleiderer and U.S. Patent No. 5,300,040 to Martin (“Martin”). Applicant respectfully traverses the Examiner’s rejection.

Claims 4 and 5 depend from Claim 1 and include all elements of Claim 1. As discussed above with respect to Claim 1, neither Aneas nor Pfleiderer, alone or in combination, disclose all elements of Claim 1. Specifically, Aneas and Pfleiderer do not disclose, teach, or suggest the element, “said needle presents a non-circular outer cross-section, while said sleeve presents a likewise non-circular inner cross-section, the outer section of said needle and inner section of said sleeve being such that said needle can slide in said sleeve, without the possibility of rotation in said sleeve,” or the element, “an edge of said sleeve opposite said stopper is provided with stop means adapted to cooperate with a complementary means provided on said plunger to lock it in position of transfer.” Applicant submits that Martin does not disclose either of these two elements, and thus, does not create a *prima facie* case of obviousness with respect to Claim 1. Additionally, Applicant submits that Martin is not properly combinable with Aneas or Pfleiderer to form a *prima facie* case of obviousness.

Martin discloses a self-locking syringe device (10) that locks by a user depressing a locking tab (40), which prevents a needle guard (12) from moving to expose the needle. (Martin, Col. 3, Lines 15-42). The structure pointed to by the Examiner is not relevant to the invention of

Claim 1, as such structure is merely implemented to “snap” a sealing plate (56) onto the end of the syringe barrel (16). (Martin, Col. 4, Lines 11-20). As can be better seen with reference to FIG. 1 of Martin, this arrangement is very different from the arrangement of the present invention, as described in Claim 1. Martin does not disclose that the pins (60) with projections (62) interact at all with a plunger, or similar mechanism, to lock it in position. Further, because the needle of Martin does not slide within a sleeve, Martin does not disclose a stop means at the edge of such a sleeve to lock a plunger in position.

Additionally, Martin does not disclose the use of a needle with a non-circular cross-section, nor does it disclose the use of a sleeve with a likewise non-circular cross section to prevent rotation. In fact, as stated above, the needle in Martin does not slide within a sleeve that could be so dimensioned. Accordingly, Martin, either alone or in combination with Aneas and/or Pfeiderer, does not disclose all the elements of Claim 1. Therefore, the Examiner’s combination of Aneas, Pfeiderer and Martin does not create a *prima facie* case of obviousness of Claim 1.

Further, Martin is not properly combinable with Aneas or Pfeiderer to form an obviousness rejection of Claim 1. More specifically, there is no motivation to combine the teachings of Martin with Aneas or Pfeiderer because Martin is directed toward solving a different problem. Martin is directed toward a safety syringe that includes a movable needle guard (12) that may be locked in position by a manually-operable locking tab (40). (Martin, Col. 3, Lines 15-38). In contrast, Aneas is directed to an apparatus for transferring fluids between a syringe and a container, and Pfeiderer is directed to an apparatus for transferring fluids between two containers. (Aneas, Col. 1, Lines 12-30; Pfeiderer, Col. 1, Lines 6-10). Thus, while Aneas and Pfeiderer may be in the same field as Martin, they do not address the same problem. As a result, there is no motivation to combine Martin with Aneas or Pfeiderer to form an obviousness rejection of Claim 1. Indeed, the Examiner has pointed to no such motivation to combine these references. Thus, the Examiner has not made a *prima facie* case of obviousness of Claim 1.

As stated above, Claims 4 and 5 contain all the elements of Claim 1. Thus, for the reasons set forth above, the Examiner has not made a *prima facie* case of obviousness with respect to Claims 4 and 5.

4. Rejections Over Aneas in View of Pfleiderer and Thibault

In paragraph 10 of the Office Action, the Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Aneas in view of Pfleiderer and PCT Publication WO 99/53886 to Thibault ("Thibault"). Applicant respectfully traverses the Examiner's rejection.

Claim 11 depends from Claim 1 and includes all elements of Claim 1. As discussed above with respect to Claim 1, neither Aneas nor Pfleiderer, alone or in combination, disclose all elements of Claim 1. Specifically, Aneas and Pfleiderer do not disclose, teach, or suggest the element, "said needle presents a non-circular outer cross-section, while said sleeve presents a likewise non-circular inner cross-section, the outer section of said needle and inner section of said sleeve being such that said needle can slide in said sleeve, without the possibility of rotation in said sleeve," or the element, "an edge of said sleeve opposite said stopper is provided with stop means adapted to cooperate with a complementary means provided on said plunger to lock it in position of transfer." Applicant submits that Thibault does not disclose either of these two elements, and thus, does not create a *prima facie* case of obviousness with respect to Claim 1. Additionally, Applicant submits that Thibault is not properly combinable with Aneas or Pfleiderer to form a *prima facie* case of obviousness.

Thibault is directed primarily to a closure assembly containing a collar (40, 240, 440, 640) for sealing a vial or similar container. (Thibault, Page 8, Lines 3-30). The reference to a fluid transferset is made only by way of example, because the collar can be used to secure a transferset to a vial. (Thibault, Page 12, Lines 25-31). Thibault does not disclose that the piercing member (466) of the transferset (250, 462, 662) has a non-circular cross-section, nor does it disclose any such means to prevent rotation of the needle in the sleeve. Additionally, as pointed out by the Examiner, Thibault discloses a lip (476) and flange (478) arrangement to retain the piercing member (466) in the tubular transfer member (464). (Thibault, Page 14, Lines 25-30). However, this arrangement does not operate to lock the piercing member in a transfer position with respect to the stopper. Instead, as stated above, the arrangement only prevents the piercing member (464) from sliding out of the transferset (462). Thus, the structure pointed to by the Examiner is not a "stop means" as defined in Claim 1.

Additionally, Thibault is not properly combinable with Aneas or Pfleiderer to form a *prima facie* case of obviousness. More specifically, there is no motivation to combine Thibault

with Aneas or Pfeiderer because Thibault is directed toward solving a different problem. As discussed above, Thibault is directed primarily to a closure assembly for a vial or similar container, and the reference in Thibault to a fluid transferset is made only by way of example. Since Thibault is not directed toward an improved transferset or similar connection device, one skilled in the art would not look to Thibault in developing a new connection device. Indeed, the Examiner has pointed to no such motivation to combine these references. Thus, the Examiner has not made a *prima facie* case of obviousness of Claim 1.

As stated above, Claim 11 contains all the elements of Claim 1. Thus, for the reasons set forth above, the Examiner has not made a *prima facie* case of obviousness with respect to Claim 1.

C. Double Patenting Rejections

1. Rejections Over Aneas in View of Pfeiderer

In paragraph 11 of the Office Action, the Examiner rejected Claims 1-3, 6-10, and 12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 2, 5, and 6 of Aneas in view of Pfeiderer. Applicant respectfully traverses the rejection.

Claims 1, 2, 5, and 6 of Aneas claim features of the device disclosed in the specification of Aneas, which is addressed in Section B above. As discussed above, the combination of Aneas and Pfeiderer does not form a *prima facie* case of obviousness with respect to Claim 1 of the present application. Particularly, neither Pfeiderer nor the claims of Aneas disclose or suggest the element “said needle presents a non-circular outer cross-section, while said sleeve presents a likewise non-circular inner cross-section, the outer section of said needle and inner section of said sleeve being such that said needle can slide in said sleeve, without the possibility of rotation in said sleeve,” or the element, “an edge of said sleeve opposite said stopper is provided with stop means adapted to cooperate with a complementary means provided on said plunger to lock it in position of transfer.” Thus, a double patenting rejection of Claim 1 over any claims of Aneas in view of Pfeiderer is inappropriate.

Claims 2, 3, 6-10, and 12 of the present application depend from Claim 1 and include all elements of Claim 1. Therefore, a double patenting rejection of Claims 2, 3, 6-10, and/or 12 of the present application over any claims of Aneas in view of Pfleiderer is inappropriate.

2. Rejection Over Aneas in view of Thibault

In paragraph 12 of the Office Action, the Examiner rejected Claim 11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 2, 5, and 6 of Aneas in view of Thibault. Applicant respectfully traverses the rejection.

Claims 1, 2, 5, and 6 of Aneas claim features of the device disclosed in the specification of Aneas, which is addressed in Section B above. As discussed above, the combination of Aneas and Thibault does not form a *prima facie* case of obviousness with respect to Claim 1 of the present application. Particularly, neither Thibault nor the claims of Aneas disclose or suggest the element “said needle presents a non-circular outer cross-section, while said sleeve presents a likewise non-circular inner cross-section, the outer section of said needle and inner section of said sleeve being such that said needle can slide in said sleeve, without the possibility of rotation in said sleeve,” or the element, “an edge of said sleeve opposite said stopper is provided with stop means adapted to cooperate with a complementary means provided on said plunger to lock it in position of transfer.” Thus, a double patenting rejection of Claim 1 over any claims of Aneas in view of Thibault is inappropriate.

Claim 11 of the present application depends from Claim 1 and includes all elements of Claim 1. Therefore, a double patenting rejection of Claim 11 of the present application over any claims of Aneas in view of Thibault is inappropriate.

3. Rejections Over Aneas in View of Martin

In paragraph 13 of the Office Action, the Examiner rejected Claims 4 and 5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 2, 5, and 6 of Aneas in view of Martin. Applicant respectfully traverses the rejection.

Claims 1, 2, 5, and 6 of Aneas claim features of the device disclosed in the specification of Aneas, which is addressed in Section B above. As discussed above, the combination of Aneas and Martin does not form a *prima facie* case of obviousness with respect to Claim 1 of the present application. Particularly, neither Martin nor the claims of Aneas disclose or suggest the element “said needle presents a non-circular outer cross-section, while said sleeve presents a

likewise non-circular inner cross-section, the outer section of said needle and inner section of said sleeve being such that said needle can slide in said sleeve, without the possibility of rotation in said sleeve,” or the element, “an edge of said sleeve opposite said stopper is provided with stop means adapted to cooperate with a complementary means provided on said plunger to lock it in position of transfer.” Thus, a double patenting rejection of Claim 1 over any claims of Aneas in view of Martin is inappropriate.

Claims 4 and 5 of the present application depend from Claim 1 and include all elements of Claim 1. Therefore, a double patenting rejection of Claims 4 and 5 of the present application over any claims of Aneas in view of Pfleiderer is inappropriate.

D. New Claim 13

Newly added Claim 13 contains the element, “said needle has a non-circular outer cross-section and said sleeve has a non-circular inner cross-section, the outer section of said needle and the inner section of said sleeve dimensioned such that said needle can slide in said sleeve without the possibility of rotation of said needle in said sleeve.” As discussed above with respect to Claims 1-12, the cited prior art (Aneas, Pfleiderer, Thibault, and Martin) does not disclose, teach or suggest this element of Claim 13. Further, as discussed above, there is no motivation to combine the cited references. Thus, the prior art cited by the Examiner cannot form a *prima facie* case of obviousness with respect to Claim 13. Applicant submits that Claim 13 is patentable and requests allowance of the same.

Appl. No. 10/091,897
Attorney Docket No. BIO-5708 (1417G P 703)
Reply to Office Action Mailed August 16, 2004



CONCLUSION

In view of the foregoing, Applicant respectfully requests reconsideration of the Examiner's rejections and allowance of Claims 1-13 in the present Application. Applicant submits that the Application is in condition for allowance and respectfully requests an early notice of the same.

Respectfully submitted,

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